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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,586	04/24/2000	MAURIZIO VALLERI	515-4183	6516

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,586	VALLERI, MAURIZIO	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- Th MAILING DATE of this communication appears on th cover sheet with th correspond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-18* is/are rejected.

7)☒ Claim(s) *9-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Amendment B, received September 21, 2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 588 539 A to Silver. Silver discloses a pharmaceutical composition which comprises either vitamin D_2 or vitamin D_3 , excipients, and calcium phosphate (p 5, claims 1 and 6). Furthemore, Silver calls for the inclusion of excipients, and specifically teaches that polyethylene glycol can be included as a stabilizer (p 5, claim 5). The reference does not disclose the amounts of vitamin D and calcium salt in the same manner claimed by applicant, and therefore there is no means for a comparison. Therefore, the burden is shifted to applicant to prove that the two formulations are patentably distinct. Therefore, the disclosure anticipates the limitations of claims 1-7.

Applicant's arguments have been fully considered but are not found to be persuasive.

For clarification purposes, Silver teaches a solid pharmaceutical composition comprising (a) vitamin D_2 or D_3, (b) an antioxidant, (c) a polyoxylalkyl stabilizer such as polyethylene glycol, and (d) an excipient or carrier selected from calcium phosphate, sorbitol, and lactose.

Applicant's argue that that Silver does not teach Calcium in combination with Vitamin D. However, as stated in the above rejection, Silver does teach a combination of vitamin D and calcium phosphate. Applicant further argues that although calcium phosphate *can* be used, it is not required, and can be exchanged for lactose or sorbitol. The examiner finds this argument to be unpersuasive. Regardless of how many alternatives are taught by the prior art reference, Silver still clearly teaches a composition comprising vitamin D and calcium phosphate, which anticipates applicant's instant claims. Additionally, Applicant argues that the present invention includes liquid paraffin or silicon oil. However, the examiner points out that these components are used in the alternative with polyethylene glycol and polypropylene glycol, and are therefore not required in applicant's claims. Lastly, applicant argues that Silver does not teach the high Calcium to vitamin D ratio that is the essence of applicant's claimed invention. The examiner respectfully disagrees. Although the examples illustrate the use of sorbitol and lactose, rather than calcium phosphate, the examples are used to show the ratio between component (a) – vitamin D, and component (d)- calcium phosphate, sorbitol, or lactose. For instance, example 3 on page 4 teaches 96% component (d) and 0.01% vitamin D. Absent any evidence to the contrary, it is the

position of the examiner that this high calcium to vitamin D ratio anticipates applicant's claims. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, and13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR-A-2 724 844 (FR '844). FR '844 discloses a composition comprising a calcium salt and and vitamin D. More specifically, FR '844 teaches that the calcium salt can be selected from the group including calcium carbonate, calcium phosphate, calcium citrate, calcium gluconate, calcium lactate, and others (p 11, claim 2). Additionally, FR '844 teaches that the vitamin D can be in the form of vitamin D_2 or vitamin D_3 (p 11, claim 3). FR '844 also teaches the presence of many well known additives, including binders, lubricants, and flavor agents. The reference also teaches the formulation in many different forms, including a sachet (p 13, claim 13). FR '844 also teaches a method to produce the formulation, comprising granulating the components and mixing them together, prior to making the final dosage form (p 13, claim 14). FR '844 does not teach all of the specific additives claimed by applicant. However, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any well known additives in the formulation. Furthermore, it is the position of the examiner that

FR '844 discloses the generic concept of applicant's invention, and the burden is shifted to applicant to show a patentable difference. Additionally, the reference does not disclose the amounts of vitamin D and calcium salt in the same manner claimed by applicant, and therefore there is no means for a comparison. Therefore, the burden is shifted to applicant to prove that the two formulations are patentably distinct. One of ordinary skill in the art would have been motivated to create a sachet formulation comprising particles of vitamin D and a calcium salt, as well as well known additives, for the treatment of calcium deficiency, based on the teachings of FR '844. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the reference does not teach the binding agents of the present invention. However, as stated in the above rejection, the reference does teach a composition comprising calcium salts, vitamin D, and known additives, such as binders. It is within the ordinary skill of the art to chose an appropriate binder for the composition, based on the references generic teaching to the inclusion of a binder. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Additionally, applicant argues that the reference only teaches 500 mg of calcium, unlike the 1-2 g claimed by applicant. The examiner respectfully disagrees and points

to examples 2, 4, 5, 6, which all teach between 1 and 2 grams of calcium. The line pointed out by applicant as disclosing 500 mg of calcium, actually teaches 400 mg of vitamin D.

Applicant further argues that the reference does not teach calcium phosphate, which is applicant's preferred salt. This argument as not persuasive for several reasons. First, applicant's independent claim does not specify calcium phosphate, but instead claims calcium salts in general. Furthermore, it is the position of the examiner that one of ordinary skill in the art would be motivated to use any well known calcium salt in the composition taught by the reference, and expect the same result.

Allowable Subject Matter

Claims 9-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Additionally, these claims must be rewritten to overcome any 112 rejections.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

aep
December 3, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600